PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61L 29/00 | A2

(11) International Publication Number: **WO 99/29353**

(43) International Publication Date: 17 June 1999 (17.06.99)

(21) International Application Number: PCT/US98/26413

(22) International Filing Date: 11 December 1998 (11.12.98)

(30) Priority Data:
08/989,791 12 December 1997 (12.12.97) US
09/045,483 20 March 1998 (20.03.98) US

(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Applications
US 08/989,791 (CIP)
Filed on 12 December 1997 (12.12.97)
US 09/045,483 (CIP)
Filed on 20 March 1998 (20.03.98)

(71) Applicant *(for all designated States except US)*: INTELLA INTERVENTIONAL SYSTEMS, INC. [US/US]; 870 Hermosa Drive, Sunnyvale, CA 94086 (US).

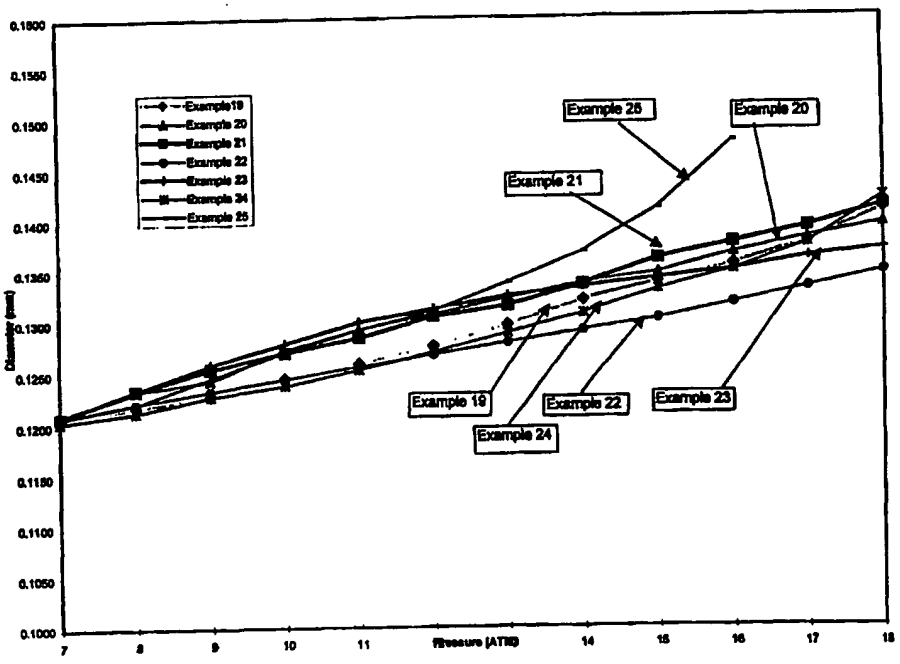
(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: THAKRAR, Ashok [US/US]; 2582 Glen Dundee Way, San Jose, CA 95148 (US). GANDHI, Deepak [US/US]; 911 Bowen Avenue, San Jose, CA 95123 (US). TENHOFF, Harm [NL/US]; 201 Ada Avenue #37, Mountain View, CA 94043 (US).

(74) Agent: ABRAHAM, David, J.; Wilson Sonsini Goodrich & Rosati, 650 Page Mill Road, Palo Alto, CA 94304-1050 (US).

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
Without international search report and to be republished upon receipt of that report.

(54) Title: MEDICAL DEVICES WITH IMPROVED PROPERTIES



(57) Abstract

Disclosed are medical devices including a polymer or polymeric composition, wherein the physical properties of the polymers or polymeric compositions or of the devices themselves are specified. Also disclosed are methods of using the devices.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania
AM	Armenia
AT	Austria
AU	Australia
AZ	Azerbaijan
BA	Bosnia and Herzegovina
BB	Barbados
BE	Belgium
BF	Burkina Faso
BG	Bulgaria
BJ	Benin
BR	Brazil
BY	Belarus
CA	Canada
CF	Central African Republic
CG	Congo
CH	Switzerland
CI	Côte d'Ivoire
CM	Cameroon
CN	China
CU	Cuba
CZ	Czech Republic
DE	Germany
DK	Denmark
EE	Estonia
ES	Spain
FI	Finland
FR	France
GA	Gabon
GB	United Kingdom
GE	Georgia
GH	Ghana
GN	Guinea
GR	Greece
HU	Hungary
IE	Ireland
IL	Israel
IS	Iceland
IT	Italy
JP	Japan
KE	Kenya
KG	Kyrgyzstan
KP	Democratic People's Republic of Korea
KR	Republic of Korea
KZ	Kazakstan
LC	Saint Lucia
LI	Liechtenstein
LK	Sri Lanka
LR	Liberia
LS	Lesotho
LT	Lithuania
LU	Luxembourg
LV	Latvia
MC	Monaco
MD	Republic of Moldova
MG	Madagascar
MK	The former Yugoslav Republic of Macedonia
ML	Mali
MN	Mongolia
MR	Mauritania
MW	Malawi
MX	Mexico
NE	Niger
NL	Netherlands
NO	Norway
NZ	New Zealand
PL	Poland
PT	Portugal
RO	Romania
RU	Russian Federation
SD	Sudan
SE	Sweden
SG	Singapore
SI	Slovenia
SK	Slovakia
SN	Senegal
SZ	Swaziland
TD	Chad
TG	Togo
TJ	Tajikistan
TM	Turkmenistan
TR	Turkey
TT	Trinidad and Tobago
UA	Ukraine
UG	Uganda
US	United States of America
UZ	Uzbekistan
VN	Viet Nam
YU	Yugoslavia
ZW	Zimbabwe

MEDICAL DEVICES WITH IMPROVED PROPERTIES

RELATED APPLICATIONS

This application is a continuation-in-part of U.S. Patent Application Serial No. 08/989,791, filed December 12, 1997, and U.S. Patent Application Serial No. 09/045,483, filed March 20, 1998.

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to medical devices with improved properties and methods of making and using the medical devices.

Description of Related Art

Polymers are often materials of choice for use in medical devices, such as catheters and PTCA balloons. For example, U.S. Patent No. 5,554,120, to Chen et al., discloses polymeric components used in forming medical devices such as catheters and balloons for dilatation catheters. U.S. Patent No. 4,469,827 discloses polymeric compositions that can be converted into shaped articles, such as tubes, cannulae, and catheters, that are useful in the medical field. Applicant notes that all documents specifically referred to in this application, including the above mentioned patents, are incorporated by reference as if reproduced in full below.

However, medical devices comprising polymers or polymeric compositions in use today suffer from a number of disadvantages. For example, such medical devices may suffer from relatively high coefficients of friction, rendering intraluminal applications undesirably difficult.

Additionally, several common polymers or polymeric compositions are brittle, such that the frequent bending and flexing required in medical devices may cause premature failure. Furthermore, other common polymers or polymeric compositions may not be biocompatible, making their use in medical devices undesirable.

There is a need, therefore, for suitable medical devices and methods of using the medical devices that solve the aforementioned problems.

SUMMARY OF THE INVENTION

A substantially non-polyester substantially non-polyamide medical device comprising polymers or polymeric compositions, wherein the glass transition temperature for the polymer or polymetric composition ranges from about 20°C to about 100°C.

A substantially non-polyester substantially non-polyamide medical device comprising polymer or polymeric compositions, wherein the polymer or polymeric compositions possess a bulk elongation ranging from about 100 to about 1000 percent, and a bulk tensile strength ranging from about five to about twelve kpsi.

A substantially non-polyester substantially non-polyamide medical device comprising polymer or polymeric compositions, wherein the polymer or polymeric compositions possess a bulk elongation ranging from about 100 to about 1000 percent, and an axial tensile strength of the substantially non-polyester substantially non-polyamide medical device ranges from about ten to about forty kpsi.

A substantially non-polyester substantially non-polyamide medical dvice comprising polymer or polymeric compositions, wherein the polymer or polymeric compositions possess a bulk elongation ranging from about 100 to about 1000 percent, and the tangential tensile strength of the

substantially non-polyester substantially non-polyamide medical device ranges from about ten to about forty kpsi.

A substantially non-polyester substantially non-polyamide intraluminal balloon comprising a polymer or polymetric composition, wherein the intraluminal balloon possesses a percent growth/atmosphere ranging from about 0.30 to about 1.60.

A medical device comprising a polymer or polymeric composition, wherein the polymer or polymetric composition possesses a bulk elongation ranging from about 500% to about 1200% and a glass transition temperature ranging from about 20°C to about 100°C.

A medical device comprising a polymer or polymeric composition, made by a method comprising of providing an aliphatic polyketone polymer incorporating the aliphatic polyketone polymer into the polymer or polymeric composition and incorporating the polymer or polymeric composition into the medical device.

A method of making a medical device comprising a composition comprising aliphatic polyketone comprising cross-linking the compiosition comprising aliphatic polyketone by eletron beam radiation, heat or ultraviolet light.

A medical device comprising aliphatic polyketone.

A composition comprising at least one aliphatic polyketone and at least one plasticizer.

A medical device comprising at least one aliphatic polyketone polymer or a composition of at least one aliphatic polyketone and at least one plasticizer.

A medical device comprising a composition that comprises an aliphatic polyketone and a thermoplastic polymer.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a plot of a balloon compliance curve showing balloon size versus balloon pressure for several different balloon materials.

DETAILED DESCRIPTION OF THE INVENTION

The applicant has surprisingly and unexpectedly discovered certain properties of polymers or polymeric compositions that result in improved performance of medical devices comprising those polymers or polymeric compositions.

Continuing, there are particular properties of polymers or polymeric compositions that result in improved performance of substantially non-polyester substantially non-polyamide medical devices comprising those polymers or polymeric compositions. For example, the glass transition temperature range of polymers or polymeric compositions used in substantially non-polyester substantially non-polyamide medical devices may affect performance of the medical device. Glass transition temperature generally depends upon factors including polymeric chain to polymeric chain interaction, molecular orientation and degree of crystallinity. As glass transition temperature increases, medical device characteristics such as balloon burst pressures may increase, resulting in improved performance. However, as glass transition temperatures increase, flexibility may decrease and catheters and balloons may become harder to push through tortuous paths. Thus, substantially non-polyester substantially non-polyamide medical devices comprising polymers or polymeric compositions that possess glass transition temperatures ranging from about 20 °C to about 100°C, more preferably from about 20°C to about 65°C, are desirable according to the invention.

Examples of inventive substantially non-polyester substantially non-polyamide medical devices comprising polymers or polymeric compositions that possess glass transition temperatures ranging from about 20 °C to about 100°C include, but are not limited to, those that comprise aliphatic polyketone (Carilon D26HM100), cross-linked aliphatic polyketone, acrylonitrile butadienestyrene (ABS), and polyvinyl alcohol.

Additionally, the bulk elongation and bulk tensile strength of polymers or polymeric compositions used in the inventive substantially non-polyester, substantially non-polyamide, medical devices may affect performance of the inventive medical device. For example, as bulk elongation increases, compliance may increase. As bulk elongation decreases, compliance may decrease. Similarly, as tensile strength increases, balloon burst strength may increase. However, as tensile strength increases, the polymer or polymeric composition may become more crystalline, with consequently more pinholing. Accordingly, substantially non-polyester substantially non-polyamide medical devices comprising polymer or polymeric compositions with bulk elongations ranging from about 100 to about 1000 percent, and bulk tensile strengths ranging from about five to about twelve kpsi are desirable according to the invention. More preferably, the inventive substantially non-polyester substantially non-polyamide medical devices comprise polymer or polymeric compositions with bulk elongations ranging from about 200 to about 600 percent, and bulk tensile strengths ranging from about seven to about ten kpsi.

Examples of inventive substantially non-polyester substantially non-polyamide medical devices comprising polymer or polymeric compositions with bulk elongations ranging from about 100 to about 1000 percent, and bulk tensile strengths ranging from about five to about twelve kpsi include, but are not limited to, those that comprise aliphatic polyketone (Carilon

D26HM100), a blend of 90 wt% aliphatic polyketone with 10 wt% poly (vinylidene fluoride), and poly(ethylene vinyl alcohol).

Additionally, the bulk elongation of polymers or polymeric compositions of which the inventive substantially non-polyester substantially non-polyamide medical devices may be comprised, and the axial tensile strength of the substantially non-polyester substantially non-polyamide medical devices, may affect performance of the inventive medical devices. For example, as bulk elongation increases, compliance may increase. As bulk elongation decreases, compliance may decrease. Similarly, as the axial tensile strength of the polymers or polymeric compositions of which the substantially non-polyester substantially non-polyamide medical device is comprised increases, the balloon burst pressure may increase. As the axial tensile strength of the polymers or polymeric compositions of which the substantially non-polyester substantially non-polyamide medical device is comprised decreases, the balloon burst pressure may decrease. Accordingly, substantially non-polyester substantially non-polyamide medical devices comprising polymer or polymeric compositions with bulk elongations ranging from about 100 to about 1000 percent, and axial tensile strengths of the substantially non-polyester substantially non-polyamide medical device ranging from about ten to about fourty kpsi are desirable according to the invention. More preferably, the substantially non-polyester substantially non-polyamide medical devices comprise polymer or polymeric compositions with bulk elongations ranging from about 200 to about 600 percent, and wherein the axial tensile strengths of the substantially non-polyester substantially non-polyamide medical device range from about 15 to about 30 kpsi.

Examples of inventive substantially non-polyester substantially non-polyamide medical devices comprising polymer or polymeric compositions

with bulk elongations ranging from about 100 to about 1000 percent, and axial tensile strengths of the substantially non-polyester substantially non-polyamide medical device ranging from about ten to about fourty kpsi include, but are not limited to, those that comprise aliphatic polyketone (Carilon D26HM100), a blend of 90 wt% aliphatic polyketone with 10 wt% poly (vinylidene fluoride), and poly(ethylene vinyl alcohol).

Additionally, the bulk elongation of polymers or polymeric compositions of which the inventive substantially non-polyester substantially non-polyamide medical devices may be comprised, and the tangential tensile strength of the substantially non-polyester substantially non-polyamide medical devices, may affect performance of the inventive medical devices. For example, as bulk elongation increases, compliance may increase. As bulk elongation decreases, compliance may decrease. Similarly, as the tangential tensile strength of the polymers or polymeric compositions of which the substantially non-polyester substantially non-polyamide medical device is comprised increases, balloon burst pressure may increase. As the tangential tensile strength of the polymers or polymeric compositions of which the substantially non-polyester substantially non-polyamide medical device is comprised decreases, balloon burst pressure may decrease. Accordingly, substantially non-polyester substantially non-polyamide medical devices comprising polymer or polymeric compositions with bulk elongations (i.e. elongation of subtantially non-oriented polymer) ranging from about 100 to about 1000 percent, and tangential tensile strengths of the substantially non-polyester substantially non-polyamide medical device (i.e. oriented polymer) ranging from about ten to about fourty kpsi are desirable according to the invention. More preferably, the substantially non-polyester substantially non-polyamide medical devices comprise polymer or polymeric compositions with bulk elongations ranging from about 200 to about 600 percent, and wherein the tangential tensile strengths of the substantially non-polyester

substantially non-polyamide medical device range from about 15 to about 30 kpsi.

Examples of inventive substantially non-polyester substantially non-polyamide medical devices comprising polymer or polymeric compositions with bulk elongations (i.e. elongation of subtantially non-oriented polymer) ranging from about 100 to about 1000 percent, and tangential tensile strengths of the substantially non-polyester substantially non-polyamide medical device (i.e. oriented polymer) ranging from about ten to about fourty kpsi include, but are not limited to, those that comprise aliphatic polyketone (Carilon D26HM100), a blend of 90 wt% aliphatic polyketone with 10 wt% poly (vinylidene fluoride), and poly(ethylene vinyl alcohol).

Additionally, the percent growth/atmosphere anywhere within the working range of a non-polyester non-polyamide intraluminal balloon may affect performance of the intraluminal balloon. Balloon percent growth/atmosphere may be calculated as:

$$\% \text{ Growth/Atm} = 100 * \frac{\text{Balloon size @ X+1 Atm - Balloon size @ X Atm}}{\text{Balloon size @ X Atm}}$$

where X is defined as $1 \leq X \leq$ Rated Burst Pressure (RBP) - 1 Atm. Performance of an intraluminal balloon may change as its % Growth/Atm changes. For example, as the percent growth/atmosphere anywhere within the working range increases, variable balloon sizing may be possible but balloon size control decreases. Accordingly, non-polyester non-polyamide intraluminal balloons comprising polymer or polymeric compositions wherein the intraluminal balloon possesses a percent growth/atmosphere of about 0.30 to about 1.60 %/Atm are desirable according to the invention. More preferably, the balloon possesses a percent growth/Atm of about 0.5 to about 1.35 %/Atm, and still more preferably the balloon possesses a percent growth/Atm of about 0.8 to about 1.3 %/Atm.

Examples of non-polyester non-polyamide intraluminal balloons comprising polymer or polymeric compositions wherein the intraluminal balloon possesses a percent growth/atmosphere of about 0.30 to about 1.60 %/Atm include, but are not limited to those that comprise a blend of about 97 wt% aliphatic polyketone and about 3 wt% triethyl acetate, and those that comprise poly (ethylene vinyl alcohol).

In another embodiment, inventive medical devices comprising a polymer or polymeric composition possessing a bulk elongation ranging from about 500% to about 1200% and a glass transition temperature ranging from about 20°C to about 100°C are desirable. More preferably, inventive medical devices comprising a polymer or polymeric composition possessing a bulk elongation ranging from about 500% to about 800% and a glass transition temperature ranging from about 20°C to about 65°C are desirable. Bulk elongations according to the invention may allow for easier polymer chain orientation and balloon blowing while the range of glass transition temperatures may provide higher strength without stiffness. inventive medical devices comprising a polymer or polymeric composition possessing a bulk elongation ranging from about 500% to about 1200% and a glass transition temperature ranging from about 20°C to about 100°C are desirable.

Examples of medical devices comprising a polymer or polymeric composition possessing a bulk elongation ranging from about 500% to about 1200% and a glass transition temperature ranging from about 20°C to about 100°C include, but are not limited to, those that comprise a blend of 90 wt% aliphatic polyketone (Carilon D26HM100) with 10 wt% poly (vinylidene fluoride), and poly(ethylene vinyl alcohol).

After much research, the inventors have established certain preferable polymers and polymeric compositions that posses the preferable physical properties discussed above. For example the properties of aliphatic polyketone polymers and polymeric compositions make them

outstanding materials of construction for medical devices according to the invention. This is because they may posses the desirable properties discussed above, in addition to reasonable biocompatibility, good processability, good dimensional stability, and good tensile strength and percent elongation.

Additionally, aliphatic polyketone polymers and compositions can be utilized in a startlingly broad range of medical devices. This is because they possess properties such as low coefficient of friction, excellent bondability to other medical device materials, excellent hydrolytic stability, and an easily tailorable Young's modulus. These properties allow a medical device designer considerable latitude in selecting the appropriate aliphatic polyketone polymer or composition to meet design needs. In particular, aliphatic polyketone polymers and compositions may be advantageously used in medical devices, including but not limited to, inflatable balloons and catheter shafts.

Of course, other polymers or polymeric compositions not comprising aliphatic polyketones may be used in the practice of this invention, so long as they satisfy the physical property characteristics outlined above. For example, polymeric compositions comprising blends of polyester and polyamides can be prepared that satisfy one or more of the physical property characteristics outlined above. Such polymeric compositions may be used in the practice of the invention.

Continuing with aliphatic polyketones, the applicant has previously disclosed in U.S. Patent Application Serial No. 08/989,791, filed December 12, 1997, incorporated by reference, compositions comprising at least one aliphatic polyketone and at least one plasticizer. Also disclosed were medical devices comprising polyketone polymer or a composition of at least one aliphatic polyketone and at least one plasticizer. Applicants have additionally disclosed in U.S. Patent Application No. 09/045,483, filed March 20, 1998, incorporated by reference, that compositions that comprise

an aliphatic polyketone and a thermoplastic polymer can be used advantageously in medical devices according to the invention.

Aliphatic polyketones are a relatively newly developed class of polymers. Therefore, with the exception of the applicant's U.S. Patent Applications Serial No. 08/989,791, filed December 12, 1997, and Serial No. 09/045,483, filed March 20, 1998, aliphatic polyketone polymers and compositions have not been previously utilized for medical device applications.

The aliphatic polyketones used in this invention are generally derived from carbon monoxide and alpha olefins. Such polyketones are generally thermoplastic in nature, and may be characterized as strong, tough, and ductile polymers. Specific aliphatic polyketone polymers are available from Shell Chemical Company (Houston, Texas) under the trademark CARILON®. Typical bulk properties for aliphatic polyketones may be:

Specific Gravity	1.24
Tensile Strength@ yield, psi	8,700 -9,200
Elongation @ yield %	22-28
@ break	300
Tensile Modulus, psi	230,000
Flexural Modulus, psi	220,000
Wear Factor	215x10-10 in^3-min/lb-ft-hr
Melting Point Deg. F	428

A wide variety of polymers may be used in the practice of this invention. Preferably, many commercially available thermoplastic polymers may be used in the practice of this invention. These thermoplastic polymers usually possess properties such as good dimensional stability, low toxicity, reasonable range of stiffness and flexibility, and good compounding properties. It should be noted that the thermoplastic polymers, and the aliphatic polyketones as well, are defined herein to include copolymers,

such as copolymers, terpolymers, etc., and derivatives of the thermoplastic polymers and the aliphatic polyketones, in addition to the homopolymer of the thermoplastic polymers and the aliphatic polyketones.

While an extremely broad range of thermoplastic polymers may be preferably used in the practice of this invention, a few thermoplastic polymers are more preferable. For example, polyamides and their derivatives may be used in the practice of this invention. Polyamides are high molecular weight polymers formed by condensation of dicarboxylic acids with diamines, condensation of ω-aminoacids, or by ring opening and polymerization of cyclic amides. Polyamides are characterized by high strength, stiffness, and hardness; high wear resistance, good slip and dry running properties, and relative non-toxicity. Additional chemistries and properties are set forth in Hans Domininghaus, Plastics for Engineers: Materials, Properties, Applications, 1993 (J. Haim & D. Hyatt, trans., Carl Hanser Verlag, publ.). Specific polyamides useful in the practice of this invention include Nylon-11 (available as BESNO® from Elf Atochem), Nylon 12 (available as VESTAMID® from Huls America), Nylon 6/12 (available from DSM).

Polyesters and their derivatives may also be used in the practice of this invention. Generally, speaking, polyesters useful in the practice of this invention include, but are not limited to, polycarbonates, and polyalkylene-terephthalates. Polyesters generally are characterized by low density, high strength, stiffness and hardness, and good slip and wear properties. Additional chemistries and properties are set forth in Hans Domininghaus, Plastics for Engineers: Materials, Properties, Applications, 1993 (J. Haim & D. Hyatt, trans., Carl Hanser Verlag, publ.). Particular polyesters useful in the practice of this invention include polyethylene terephthalate (available as TRAYTUF® from Shell), Poly(trimethylene) terephthalate (available from Shell), Polybutylene terephthalate (available as CRASTIN® from Dupont),

PETG Copolyester (available from Eastman), and polyester elastomers such as HYTREL® (available from Dupont).

Polyether-blockamides and their derivatives are also useful polymers in the practice of this invention. Polyether-blockamides are thermoplastic elastomers that are generally characterized by, among other properties, good flexibility and impact resistance at low temperatures, good dynamic properties (e.g. resilience, and hysteresis), superior processing properties, and good compatibility with various fillers. Additional chemistries and properties are set forth in Elf Atochem, Pebax: Basis of Performance (Polyether Block Amides), (available from Elf Atochem). Examples of such polyether-blockamides are available as PEBAX® from Elf Atochem. In an embodiment, the inventive medical devices comprise non-polyamide, non-polyester polymers or polymeric compositions.

Polyurethane and its derivatives are also useful in the practice of this invention. Polyurethanes may be obtained by a variety of chemistries. One of the most common is the polycondensation of isocyanate monomers with alcohols or other materials containing reactive oxygen moieties (eg. polyesters), although other chemistries may also be used. Polyurethanes are characterized by rapid curing, low shrinkage, good adhesion, high chemical resistance, good flexibility, and safe handling of the cured polymer. Additional chemistries and properties are set forth in Hans Domininghaus, Plastics for Engineers: Materials, Properties, Applications, 1993 (J. Haim & D. Hyatt, trans., Carl Hanser Verlag, publ.). Particular polyurethanes useful in the practice of this invention include TECOFLEX® EG85A available from TherMedics, Inc.), PU/PC blends (such as TEXIN® available from Bayer), and PELLETHANE® 2363 available from Dow Plastics.

Polyolefins and their derivatives may also be used in the practice of this invention. Polyolefins can be synthesized using a broad variety of chemistries, but are most often made using a catalyzed free radical

polymerization reaction. Generally speaking, polyolefins are characterized by relatively low density, high toughness, high chemical resistance, and good processability and machinability. Additional chemistries and properties are set forth in Hans Domininghaus, Plastics for Engineers: Materials, Properties, Applications, 1993 (J. Haim & D. Hyatt, trans., Carl Hanser Verlag, publ.). Polyolefins that are preferable in the practice of this invention include polyethylenes, polypropylenes, polyolefin copolymers, polyolefin terpolymers, polybutylene, polypentylene, and polyolefin blends. Specific examples of polyolefins useful in the practice of this invention include polyethylene (available as AFFINITY® PL 1850 from Dow Chemical), terpolymer polyolefin blends (available as SLX 9090 from Exxon), and polypropylene (available as PDC 1188 from Montel).

Polyacrylonitrile and its derivatives may also be used in the practice of this invention. Polyacrylonitrile can be synthesized using a broad variety of chemistries, but are most often made using a catalyzed free radical polymerization reaction. Generally speaking, polyacrylonitrile is characterized by relatively high strength, high modulus of elasticity, and high impact strength. Additional chemistries and properties are set forth in Hans Domininghaus, Plastics for Engineers: Materials, Properties, Applications, 1993 (J. Haim & D. Hyatt, trans., Carl Hanser Verlag, publ.). Polyacrylonitriles that are useful in the practice of this invention include copolymers that include polyacrylonitrile, such as poly(styrene/acrylonitrile), and poly(acrylonitrile-butadiene-styrene). Specific examples of polyacrylonitrile useful in the practice of this invention include DOLAN® available from Hoechst.

Polyacetal and its derivatives may also be used in the practice of this invention. Polyacetals are polymerized from formaldehyde and are technically called polyoxymethlyenes. Polyacetals are characterized by their strength, stiffness, and hardness, and are stable over a wide range of

physical conditions. Additional information regarding chemistries and properties may be found in Modern Plastics Encyclopedia, B-69 (1997). Specific examples of polyacetals useful in the practice of this invention include DELRIN® (available from E. I. Du Pont), ULTRAFORM® (available from BASF Corporation's Ultraform Co.), and CELCON® (available from Hoechst-Celanese).

Polyvinylidene fluoride and its derivatives can also be used in the practice of this invention. Polyvinylidene fluoride can be synthesized in a variety of ways; the most preferable way being free radical polymerization of vinylidene fluoride monomer. Polyvinylidene fluoride is generally characterized by high mechanical strength, stiffness, and toughness, good toughness, and good chemical resistance. Additional chemistries and properties are set forth in Hans Domininghaus, Plastics for Engineers: Materials, Properties, Applications, 1993 (J. Haim & D. Hyatt, trans., Carl Hanser Verlag, publ.). Specific polyvinylidene fluorides useful in the practice of this invention include 1015/0078 available from Solvay.

Other ingredients and materials besides aliphatic polyketones, other polymers and polymeric compositions may be used in the compositions according to the invention. For example, additives such as processing aids, including stearates, or low molecular weight waxes; antioxidants; colorants; or other conventional additives may be added. These additives may be used separately or in combinations, according to the desired final properties of the inventive compositions. The use of such additives in medical devices is customary, is well understood by one of skill in the art, and is within the scope of the invention.

Three types of additives that are preferable are coupling agents, plasticizers, and cross-linkers. Coupling agents useful in the practice of this invention can be of a wide variety of types. Generally speaking, the coupling agents useful in the practice of the invention share the characteristics that they affect the interfacial properties of the recited

aliphatic polyketones and other polymers and polymeric compositions in a way that enhances the physical properties of the medical device that comprises the compositions. Preferable coupling agents include titanium and/or zirconium coupling agents, and polymeric coupling agents.

Titanium and/or zirconium coupling agents are generally tetrafunctional organo-metallic compounds whose central metal tetravalency is conducive to electron sharing. This property makes them good candidates for modifying the interfacial properties of the recited polymers and polymeric compositions. Titanium coupling agents come in a variety of forms, including monoalkoxy, chelates, coordinates, quat salts, neoalkoxy, and cycloheteroatom. Zirconium coupling agents are also available in a variety of forms, including neoalkoxy zirconates. Such coupling agents may be obtained from Kenrich Petrochemicals (140 East 22nd Street, Bayonne NJ) under the trademark KEN-REACT®. Additional information regarding the properties of titanium and zirconium coupling agents, including information regarding use and incorporation, may be found in Salvatore J. Monte, Ken-React Reference Manual (1993) (Kenrich Petrochemicals, publ.).

Titanium and/or zirconium coupling agents may be used in an amount effective to optimize the physical properties of the medical device that comprises a composition comprising the coupling agents. More preferably, the titanium or zirconium coupling agents may be present in an amount of 0.1 to 5.0 weight percent based on the total weight of the composition. Most preferable is 1% weight percent of the coupling agent.

Generally, the polymeric coupling agents according to the invention can be selected using a few rules. First, the polymeric coupling agents may be a polymer that is made up of chemically distinct sections, some of which are miscible with the aliphatic polyketone, and some of which are miscible with another thermoplastic polymer. Of course, when additional polymers are present in the composition, the polymeric coupling agent or agents may

be miscible with them as well. Additionally, the polymeric coupling agent is more effective when its sections are of higher molecular weight than the corresponding components of the composition. Finally, block copolymers and graft copolymers are the most widely used polymeric coupling agents, and therefore are more likely to be readily available, although other types of polymeric coupling agents may be used as appropriate. Additional information regarding polymeric coupling agents, including use and incorporation, may be found in Sudhin Datta and David J. Lohse, Polymeric Compatibilizers: Uses and Benefits in Polymer Blends (1996) (Carl Hanser Verlag, publ.).

A preferable class of polymeric coupling agents includes epoxy modified polyolefins, most preferably ethylene - n-butyl acrylate - maleic anhydride terpolymers and ethylene - ethyl acrylate - maleic anhydride terpolymers. Specific examples of polymeric coupling agents useful in the practice of this invention include POLYBOND® (available from Uniroyal Chemical), and LOTADER® MAH (available from Elf AtoChem). Polymeric coupling agents, when used, may be present in an amount effective to optimize the physical properties of the medical device that comprises a composition comprising the coupling agents. More preferably, the polymeric coupling agents may be present in an amount of about 0.1 to 5 weight percent based on the total weight of the composition. Most preferable is about 1% by weight of the coupling agent, based on the total weight of the composition.

Additionally, the properties of the medical devices comprising polymers or polymeric compositions according to the invention may be improved by using plasticizers. Plasticizers are materials that may be added to polymeric materials primarily to improve flexibility. In addition, plasticizers may reduce melt viscosity and lower the glass transition temperature of the polymeric materials. By varying the level of plasticizer, it may be possible to vary the final properties of the plasticized polymeric

material. Plasticizers usable with the compositions according to the present invention preferably are polar, although nonpolar plasticizers may also be used.

Examples of plasticizers include, but are not limited to aromatic sulfonamides, aromatic phosphate esters, alkyl phosphate esters, alkyl esters, citrate esters, butyl benzosulfonamides, acetate, adipate, amides, azelates, epoxides, glutarates such as polyester glutarate, N,N-dimethyl caprylamide capramide, N,N-dimethyl oleamide, epoxidized glycol dioleate, and analogs and derivatives and mixtures thereof.

The plasticizers used in this invention are known to one of skill in the art and are readily available from conventional suppliers. For example, citrate esters are derived from citric acids, generally have benign toxicology, and are available as CITROFLEX® from Morflex, Inc (Greensboro, NC). Butyl benzosulfamides generally are light yellow liquids, having a pleasant odor, and are available as PLASTHALL® from the C. P. Hall Company (Chicago , Illinois). Further discussion of suitable plasticizers can be found in Modern Plastics Encyclopedia, C-99-108 (1997).

Preparing compositions according to the invention can be accomplished in a variety of ways. One of the most straightforward is compounding of the various ingredients in the composition. Compounding according to the invention can be done according to methods known in the art, such as extrusion. Such methods are generally described in Two Phase Polymer Systems, 69-91 (1991)(L. a. Utracki, ed.). In addition, other ways of preparing the recited composition might be used, including preparing polymeric alloys, and other methods known to one of skill in the art.

Excessive use of plasticizer in compositions according to the invention should be avoided because it may lead to blooming or leaching of the plasticizer and/or phase separation. In a preferable embodiment, plasticizer may be present in an amount effective to optimize the physical

properties of the medical device that comprises a composition comprising the plasticizer. More preferable amounts of plasticizers incorporated into the compositions according to the invention range from about 0.01 to about 20 weight percent on the total composition weight, most preferably from about 5 to about 20 weight percent on the total composition weight.

Furthermore, cross-linkers may be used in the practice of a preferable embodiment of this invention. Crosslinkers function generally to link together polymer chains into a three dimension structure. Crosslinkers can be divided into at least two groups: internal and external. Both external and internal crosslinkers can be used in the practice of this invention. Internal crosslinkers are monomers or oligomers that are structurally incorporated into the polymeric backbone of the polymers to be crosslinked. Internal crosslinkers may be existing functionalities in the polymer (such as double bonds in unsaturated polyolefins), or may be functionalities added specifically for the purpose of creating crosslinking capability. External crosslinkers, by comparison, are induced to link already substantially polymerized polymers, and are mixed together with the polymers to be crosslinked. Preferable external crosslinkers include multifunctional monomers or oligomers. Especially preferable external crosslinkers include di- or tri-functional monomers. Most preferable crosslinkers include ethylene glycol dimethacrylate, triallyl isocyanurate (available as PERKALINK® 301 from Akzo Nobel), triallyl cyanurate (available as PERKALINK® 300 from Akzo Nobel), or triallyl 1,3,5-triazine-2,4,6(1H,3H,5H)-trione (available from SAF, Inc.).

The composition of medical devices according to the invention may be cross linked before or after it had been formed. In a preferable embodiment, the medical device or its precursor is first formed, and then crosslinked. While the way of crosslinking the inventive medical devices will depend primarily upon the crosslinkers used, a preferable way of crosslinking the inventive recited compositions is by gamma or electron

beam radiation techniques. When EB curing, it is preferable to use about 1.5 MeV source operating at about ten mA. Another preferable way of crosslinking the inventive recited compositions is by exposure to heat or high energy ultraviolet (UV) light. The degree of crosslinking can be controlled by adjusting the ratio of crosslinker added to the amount of other material present in the composition, or by adjusting the amount of radiation (electron beam or UV), heat supplied to crosslink the composition. Generally, in a preferable embodiment, the amount of crosslinker may be present in an amount effective to optimize the physical properties of the medical device that comprises the composition comprising the crosslinker. In a more preferable embodiment, the crosslinker may be present in an amount of about 0.1 to about 5 weight percent on the total composition weight, most preferably about 1 weight percent on the total composition weight.

The ingredient concentrations of the recited inventive compositions may vary from embodiment to embodiment. In a preferable embodiment, the compositions making up the inventive medical device may have from about 1 to about 99 weight percent aliphatic polyketone, more preferably about 5 to about 95 weight percent aliphatic polyketone, based on the total composition weight. Additionally, preferably the compositions making up the inventive medical device may have from about 1 to about 99 weight percent other polymer, more preferably about 5 to about 95 weight percent other polymer, based on the total composition weight. Miscellaneous other additives or materials included in the inventive compositions may be included in a preferable amount of about zero to about five weight percent on the total composition weight, more preferably from about 0.01 to about 5 weight percent on the total composition weight. Preferably, the total amount of plasticizers, additives and other materials is less than about 20 weight percent of based on the total composition weight.

Conventional methods for making polymeric medical devices can be easily adapted by one of skill in the art to making medical devices from the compositions of the present invention. This is because the compositions according to the invention can be worked using techniques that are conventional in the polymer art. In particular, catheter balloons having oriented wall materials of the inventive composition can be made according to the general teachings of Levy, U. S. Patent No. Re 33,561, and Jackowski et al, U. S. Patent No. 5,055,024.

Generally speaking, polymers and polymeric compositions according to the invention can be used with existing medical device architectures, or can be used to create entirely new devices based on the superior properties of the inventive compositions. For example, the inventive compositions can be used in conventional intraluminal catheters shafts, replacing polyethylene or polyurethane. Alternatively, the inventive compositions may be used to create surgical tools and implements. In a proper formulation, the recited polymers and polymeric compositions may even be able to be used in long-term implant devices, such as stents, pacemakers, or bone or cartilage replacements. In a preferable embodiment, the recited polymers or polymeric compositions can be used to create balloon catheters having balloons with improved properties. The inventive medical devices are preferably minimally invasive, more preferably the medical device comprises an intraluminal tubular member, still more preferably the medical device comprises an intraluminal balloon. The inventive medical device preferably comprises a percutaneous device: alternatively the medical device preferably comprises a non-percutaneous device. In a preferable embodiment, the inventive medical device comprises either a single balloon or multiple balloons. In another preferable embodiment wherein the medical device comprises a balloon, the balloon wall material is biaxially oriented. In yet another preferable embodiment wherein the medical device comprises a balloon, the balloon is about 1.0 to 12 mm in diameter.

An example of inventive medical devices is the combination of known multiple balloon catheter architectures with the recited polymers or polymeric compositions. In Jang, U. S. Patent No. 4,744,366, a multiple balloon catheter architecture is disclosed. The term multiple balloon is used herein to mean more than one balloon. The materials of construction disclosed for use as catheter balloon materials are polyvinyl chloride, polyester, and polyethylene. These materials can be advantageously substituted with the recited polymers or polymeric compositions. Such a substitution may result in balloons with lower coefficients of friction and improved folding properties, thus enhancing the balloon's and overall catheter system's performance.

Other known medical device architectures may be adapted for use with polymers and polymeric compositions according to the invention. For example Corso, Jr. et al. (U.S. Patent No. 5,281,200), Yock (U.S. Patent No. 5,300,085), Solar (U.S. Patent No. 5,531,690), Euteneuer et al. (U.S. Patent No. 5,567,203), Solar (U.S. Patent No. 5,569,199), Burns (U.S. Patent No. 5,569,201), and Hernandez et al. (U.S. Patent No. 5,607,406) all disclose structures that may be adapted for use with the present invention, using polymer techniques well known in the art.

It will be apparent to those skilled in the art that various modifications and variations can be made in the apparatus and methods of the present invention without departing from the spirit or scope of the invention. Thus, it is intended that the present invention cover the modifications and variations of this invention provided they come within the scope of the appended claims and their equivalents. Additionally, the following examples are appended for the purpose of illustrating the claimed invention, and should not be construed so as to limit the scope of the claimed invention.

Examples

Physical properties of the medical device compositions including aliphatic polyketones and thermoplastic polymers according to the invention were compared with conventional medical device materials, particularly polyester and plasticized nylon. The tests were performed on both standard test pieces and sample balloons according to the following procedures.

The tensile properties of the balloons were measured using a Chatillon tensile tester model TCD 200. In this procedure, one end of the cylindrical part of the balloon was attached to the lower jaw and the other end was attached to the upper jaw which was then attached to a load cell. The distance between the two jaws was measured and the sample was pulled at 0.5 inch/minute until torn. Total deflection and the force gauge reading were recorded . The axial and tensile properties of the tested balloon and its elongation at yield were calculated as follows:

Axial Tensile Strength = Force / (Double Wall thickness/2) * PI * Diameter of the Balloon

% Elongation = {(Final length -Original length)/Original length} * 100

Tangential Tensile = (Balloon Burst Press. X Dia.)/ Double wall thickness

The coefficient of friction was measured for catheter shafts by wrapping the sample catheter shaft a full 360 degrees (2π) around a pulley made out of polyacetal material. A known tension (T1) was placed at the one end of the catheter shaft and the catheter shaft was pulled from the other end. The resulting dynamic tension (T2) was measured using a Chatillon tensile tester. The coefficient of friction was calculated using the following equation:

$f = (2\pi) \ln (T2/T1)$

where f = coefficient of friction

T1= known tension at the bottom of the shaft

T2 = dynamic tension

Stiffness of the catheter shafts were tested using a three point bending method where an approximately 2 inch long piece of a shaft was deflected on a supported beam under the action of a centrally located point load. The ratio of deflection to sample length was less than or equal to 0.06. Using the following equation the stiffness and modulus of elasticity were calculated.

$$\delta = (F.L^3)/ (48.EI) = (F.L^3)/ (48.Sb)$$

$$\text{Hence, } Sb = EI = (F.L^3)/ (48.\delta)$$

δ = deflection, mm

Sb = bending stiffness of the sample in $N\text{-}mm^2$

F = force applied, Newtons

L = length, mm

E = modulus of elasticity, N/mm^2

I = moment of inertia, Ix = Iy of the beam X section about the neutral axis, mm^4

Balloon burst tests were carried out using a Crescent Design's Hydraulic Burst -Leak Tester Model 100, according to the manufacturer's instructions.

Example 1:

A molding composition was prepared by compounding 30 weight percent of aliphatic polyketone R-1000 (available from Shell Chemical Company) with 70 weight percent PEBAX® 6333 (available from Elf Atochem). The composition was compounded on a 27 mm Leistritz twin screw extruder, using a conventional homogenizing screw design. The screw speed was 345 RPM and the melt temperature was 440 Deg. F. The extruded blend was pelletized and collected. This blend was then re-extruded into a 0.019/0.038" ID/OD tube using a 25mm single screw extruder. The barrel temperature ranged from 420 Deg. F to 480 Deg. F from feeding zone to the die head respectively. Test pieces, including 2.5 mm diameter balloons were prepared using conventional techniques. The test pieces were then tested, with the results as shown in Tables 1 and 2.

Example 2:

A molding composition was prepared by compounding 10 weight percent of aliphatic polyketone R-1000 (available from Shell Chemical Co.) with 17 weight percent butyl benzosulfonamide (available as PLASTHALL® from C. P. Hall Company), and 73 weight percent nylon 12 (available as L2106F from Huls America). The composition was compounded on a 27 mm Leistritz twin screw extruder, using a conventional homogenizing screw design. The screw speed was 345 RPM and the melt temperature was 470 Deg. F. The extruded blend was pelletized and collected. This blend was then re-extruded into a 0.019/0.038" ID/OD tube using a 25mm single screw extruder. The barrel temperature ranged from 450 Deg. F to 490 Deg. F from feeding zone to the die head respectively. Test pieces, including 2.5 mm diameter balloons were prepared using conventional techniques. The test pieces were then tested, with the results as shown in Tables 1 and 2.

Example 3:

A molding composition was prepared by compounding 75 weight percent of aliphatic polyketone R-1000 (available from Shell Chemical Co.) with 25 weight percent nylon 12 (available as L2106F from Huls America). The composition was compounded on a 27 mm Leistritz twin screw extruder, using a conventional homogenizing screw design. The screw speed was 345 RPM and the melt temperature was 470 Deg. F. The extruded blend was pelletized and collected. This blend was then re-extruded into a 0.019/0.038" ID/OD tube using a 25mm single screw extruder. The barrel temperature ranged from 450 Deg. F to 490 Deg. F from feeding zone to the die head respectively. Test pieces, including 2.5 mm diameter balloons were prepared using conventional techniques. The test pieces were then tested, with the results as shown in Tables 1 and 2.

Example 4:

Polyketone Resin (CARILON® R-1000, available from Shell Chemical, Akron, OH) was extruded into a 0.019/0.038" ID/OD tube using a 25mm single screw extruder. The barrel temperature ranged from 450 Deg. F to 490 Deg. F from feeding zone to the die head respectively. Test pieces, including 2.5 mm diameter balloons were prepared using conventional techniques. The test pieces were then tested, with the results as shown in Tables 1 and 2.

Comparative Example 5:

Polyester Resin (TRAYTUF® available from Shell Chemical, Akron, OH) was extruded into a 0.019/0.038" ID/OD tube using a 25mm single

screw extruder. The barrel temperature ranged from 520 Deg. F to 560 Deg. F from feeding zone to the die head respectively. Test pieces, including 2.5 mm diameter balloons were prepared using conventional techniques. The test pieces were then tested, with the results as shown in Tables 1 and 2.

Comparative Example 6:

Plasticized Polyamide resin (VESTAMID® L-2124, available from Huls America) was extruded into a 0.019/0.038" ID/OD tube using a 25mm single screw extruder. The barrel temperature ranged from 420 Deg. F to 460 Deg. F from feeding zone to the die head respectively. Test pieces, including 2.5 mm diameter balloons were prepared using conventional techniques. The test pieces were then tested, with the results as shown in Tables 1 and 2.

Example 7:

A molding composition of 90 weight percent of aliphatic polyketone R-1000 (available from Shell Chemical Co.) was prepared by plasticizing with 10 weight percent of Triethyl Citrate (available from Moreflex as CITROFELX®). The composition was compounded on a 27 mm Leistritz twin screw extruder, using a conventional homogenizing screw design. The screw speed was 345 RPM and the melt temperature was 250 C. The extruded blend was pelletized and collected. This blend was then re-extruded into a 0.019/0.038" ID/OD tube using a 25mm single screw extruder. The barrel temperature ranged from 440 Deg. F to 490 Deg. F from feeding zone to the die head respectively. Test pieces, including 2.5 mm diameter balloons were prepared using conventional techniques. The test pieces were then tested, with the results as shown in Tables 1 and 2.

Example 8:

A molding composition is prepared by compounding 30 weight percent of aliphatic polyketone R-1000 (available from Shell Chemical Co.) with 70 weight percent nylon 12 (available as L2106F from Huls America). The composition is compounded on a 27 mm Leistritz twin screw extruder, using a conventional homogenizing screw design. The screw speed is 345 RPM and the melt temperature was 470 Deg. F. The extruded blend is pelletized and collected. This blend is then re-extruded into a 0.019/0.038" ID/OD tube using a 25mm single screw extruder. The barrel temperature ranges from 450 Deg. F to 490 Deg. F from feeding zone to the die head respectively. Test pieces, including 2.5 mm diameter balloons are prepared using conventional techniques.

Example 9:

A molding composition was prepared by compounding 75 weight percent of aliphatic polyketone R-1000 (available from Shell Chemical Co.) with 25 weight percent PEBAX® 6333 (available from Elf Atochem). The composition is compounded on a 27 mm Leistritz twin screw extruder, using a conventional homogenizing screw design. The screw speed is 345 RPM and the melt temperature was 470 Deg. F. The extruded blend is pelletized and collected. This blend is then re-extruded into a 0.019/0.038" ID/OD tube using a 25mm single screw extruder. The barrel temperature ranges from 450 Deg. F to 490 Deg. F from feeding zone to the die head respectively. Test pieces, including 2.5 mm diameter balloons are prepared using conventional techniques.

Example 10:

A molding composition was prepared by compounding 10 weight percent of aliphatic polyketone R-1000 (available from Shell Chemical Co.) with 10 weight percent butyl benzosulfonamide (available as PLASTHALL® from C. P. Hall Company), and 80 weight percent nylon 12 (available as L2106F from Huls America). The composition is compounded on a 27 mm Leistritz twin screw extruder, using a conventional homogenizing screw design. The screw speed is 345 RPM and the melt temperature was 470 Deg. F. The extruded blend is pelletized and collected. This blend is then re-extruded into a 0.019/0.038" ID/OD tube using a 25mm single screw extruder. The barrel temperature ranges from 450 Deg. F to 490 Deg. F from feeding zone to the die head respectively. Test pieces, including 2.5 mm diameter balloons are prepared using conventional techniques.

Example 11:

A molding composition was prepared by compounding 10 weight percent of aliphatic polyketone R-1000 (available from Shell Chemical Co.) with 9 weight percent butyl benzosulfonamide (available as PLASTHALL® from C. P. Hall Company), 80 weight percent nylon 12 (available as L2106F from Huls America), and 1 weight percent triallyl isocyanurate (available as PERKALINK® from Akzo Nobel). The composition is compounded on a 27 mm Leistritz twin screw extruder, using a conventional homogenizing screw design. The screw speed is 345 RPM and the melt temperature was 470 Deg. F. The extruded blend is pelletized and collected. This blend is then re-extruded into a 0.019/0.038" ID/OD tube using a 25mm single screw extruder. The barrel temperature ranges from 450 Deg. F to 490 Deg. F from feeding zone to the die head respectively. Test pieces, including 2.5 mm diameter balloons are prepared using conventional techniques. The test pieces are then crosslinked using electron beam radiation.

Example 12:

The molding composition of Example 3 is extruded into a flexible elongate tubular member having a 3 French diameter and a length of 150 centimeters. The structure of the tubular member is generally disclosed in U.S. Patent 5,725,535 to Hegde et al. The tubular member is then incorporated into a multiple balloon stent delivery catheter, which has the structure as disclosed in U.S. Patent 5,725,535. The catheter is used as is disclosed in U.S. Patent 5,725,535 to deliver a stent in a coronary vessel.

Example 13:

The molding composition of Example 3 is extruded into a flexible balloon having a two millimeter diameter. The structure of the balloon is generally disclosed in U.S. Patent 5,725,535 to Hegde et al. The balloon is then incorporated into a multiple balloon stent delivery catheter, which has the structure as disclosed in U.S. Patent 5,725,535. The catheter is used as is disclosed in U.S. Patent 5,725,535 to deliver a stent in a coronary vessel via inflation of the balloon.

Example 14:

A molding composition of 89 weight percent of aliphatic polyketone R-1000 (available from Shell Chemical Company) was prepared by plasticizing using 11 weight percent butyl benzosulfonamide (available as PLASTHALL® from C. P. Hall Company). The composition was compounded on a 27 mm Leistritz twin screw extruder, using a conventional homogenizing screw design. The screw speed was 345 RPM and the melt temperature was 250 C. The extruded blend was pelletized and collected. This blend was then re-extruded into a 0.019/0.038" ID/OD

tube using a 25mm single screw extruder. The barrel temperature ranged from 440 Deg. F to 490 Deg. F from feeding zone to the die head respectively. Test pieces, including 2.5 mm diameter balloons were prepared using conventional techniques. The test pieces were then tested, with the results as shown in Tables 1 and 2.

Example 15:

A molding composition of 95 weight percent of aliphatic polyketone R-1000 (available from Shell Chemical Company) is prepared by plasticizing using 5 weight percent butyl benzosulfonamide (available as PLASTHALL® from C. P. Hall Company). The composition is compounded on a 27 mm Leistritz twin screw extruder, using a conventional homogenizing screw design. The screw speed is 345 RPM and the melt temperature was 250 C. The extruded blend is pelletized and collected. This blend is then re-extruded into a 0.019/0.038" ID/OD tube using a 25mm single screw extruder. The barrel temperature ranges from 440 Deg. F to 490 Deg. F from feeding zone to the die head respectively. Test pieces, including 2.5 mm diameter balloons are prepared using conventional techniques.

Example 16:

A molding composition of 95 weight percent of aliphatic polyketone R-1000 (available from Shell Chemical Co.) is prepared by plasticizing with 5 weight percent of Triethyl Citrate (available from Moreflex as CITROFELX®). The composition is compounded on a 27 mm Leistritz twin screw extruder, using a conventional homogenizing screw design. The screw speed is 345 RPM and the melt temperature was 250 C. The

extruded blend is pelletized and collected. This blend is then re-extruded into a 0.019/0.038" ID/OD tube using a 25mm single screw extruder. The barrel temperature ranges from 440 Deg. F to 490 Deg. F from feeding zone to the die head respectively. Test pieces, including 2.5 mm diameter balloons are prepared using conventional techniques.

TABLE 1

Example Numbers	Coefficient of Friction		Balloons Properties		
	IN AIR	IN WATER	Tensile psi	Elongation %	Burst Pres. atm.
1	0.1214	0.1160	13128	188	10
2	0.1390	0.1011	14391	147	24
3	0.1045	0.1028	37220	74	22
4	0.100	0.084	24870	72	24
5 (Comparative)	0.090	0.073	28000	50	27
6 (Comparative)	0.160	0.110	17900	67	17
7	0.116	0.107	19200	59	18
14	0.120	0.090	19600	70	17

TABLE 2

Example Numbers	Bending Stiffness N-mm2	Young's Modulus of Elasticity N/mm2
1	15.0	2041
2	17.0	1499
3	26.0	1967
4	23.6	1685
5 (Comparative)	111.0	8455
6 (Comparative)	9.9	1846
7	18.2	1846
14	17.6	1703

Example 17:

A molding composition was prepared by compounding 87 weight percent aliphatic polyketone (Carilon DX26HW100 available from Shell Chemical) with 10% polyvinylidenen Fluoride (PVDF 1015/0078, available from Solvay) and 3% Triallyl1,3,5 Triazine-2,4,6 Trione. This composition was compounded on a 27 m Leistritz twin screw extruder, using a conventional screw design. This blend was then extruded into a 0.021/0.038" ID/OD tube using a small single screw extruder. This tube was e-beam radiated to 15 MegaRad dose using a commercial e-beam facility. Test pieces including 2.5 mm diameter balloons were prepared using conventional techniques.

Example 18:

A molding composition was prepared by compounding 97 weight percent aliphatic polyketone (Carilon DX2HW100 available from Shell Chemical) with 3% Triallyl-1,3,5 Triazine-2,4,6 Trione. This composition was compounded on a 27 mm Leistritz twin screw extruder, using a conventional screw design. This blend was then extruded into a 0.021/0.038" ID/OD tube using a small single screw extruder. This tube was e-beam radiated to 15MegaRad dose using a commercial e-beam facility. Test pieces including 2.5 mm diameter balloons were prepared using conventional techniques.

Example 19:

A balloon compliance curve was generated for a balloon having a composition of substantially 100% aliphatic polyketone as follows. The balloon was attached to a standard burst tester (Cresent Design Model 1000 or equivalent). The balloon was then submerged into a 37 degree Celsius water bath. The burst tester was then activated, and increased the internal balloon pressure in a series of steps. A snap gauge was used at each pressure step to measure the outer diameter of the balloon. The results are recorded in Table III, and plotted in FIG. 1.

Example 20:

A balloon compliance curve was generated for a balloon having a composition of PEBAX® (available from Elf Atochem) as follows. The balloon was attached to a standard burst tester (Cresent Design Model 1000 or equivalent). The balloon was then submerged into a 37 degree Celsius water bath. The burst tester was then activated, and increased the internal balloon pressure in a series of steps. A snap gauge was used at each pressure step to measure the outer diameter of the balloon. The results are recorded in Table III, and plotted in FIG. 1.

Example 21:

A balloon compliance curve was generated for a balloon having a composition of nylon as follows. The balloon was attached to a standard burst tester (Cresent Design Model 1000 or equivalent). The balloon was then submerged into a 37 degree Celsius water bath. The burst tester was then activated, and increased the internal balloon pressure in a series of steps. A snap gauge was used at each pressure step to measure the outer diameter of the balloon. The results are recorded in Table III, and plotted in FIG. 1.

Example 22:

A balloon compliance curve was generated for a balloon having a composition of polyethylene terephthalate as follows. The balloon was attached to a standard burst tester (Cresent Design Model 1000 or equivalent). The balloon was then submerged into a 37 degree Celsius water bath. The burst tester was then activated, and increased the internal balloon pressure in a series of steps. A snap gauge was used at each pressure step to measure the outer diameter of the balloon. The results are recorded in Table III, and plotted in FIG. 1.

Example 23:

A balloon compliance curve was generated for a balloon having a composition of a nylon blend as follows. The balloon was attached to a standard burst tester (Cresent Design Model 1000 or equivalent). The balloon was then submerged into a 37 degree Celsius water bath. The burst tester was then activated, and increased the internal balloon pressure in a series of steps. A snap gauge was used at each pressure step to measure the outer diameter of the balloon. The results are recorded in Table III, and plotted in FIG. 1.

Example 24:

A balloon compliance curve was generated for a balloon having a composition of a blend of aliphatic polyketone and polyvinylidine fluoride as follows. The balloon was attached to a standard burst tester (Cresent Design Model 1000 or equivalent). The balloon was then submerged into a 37 degree Celsius water bath. The burst tester was then activated, and

increased the internal balloon pressure in a series of steps. A snap gauge was used at each pressure step to measure the outer diameter of the balloon. The results are recorded in Table III, and plotted in FIG. 1.

Example 25:

A balloon compliance curve was generated for a balloon having a composition of butyl benzosulfonamide-plasticized aliphatic polyketone as follows. The balloon was attached to a standard burst tester (Cresent Design Model 1000 or equivalent). The balloon was then submerged into a 37 degree Celsius water bath. The burst tester was then activated, and increased the internal balloon pressure in a series of steps. A snap gauge was used at each pressure step to measure the outer diameter of the balloon. The results are recorded in Table III, and plotted in FIG. 1.

Example 26:

A balloon compliance curve was generated for a balloon having a composition of triethyl citrate plasticized-aliphatic polyketone plasticzed with as follows. The balloon was attached to a standard burst tester (Cresent Design Model 1000 or equivalent). The balloon was then submerged into a 37 degree Celsius water bath. The burst tester was then activated, and increased the internal balloon pressure in a series of steps. A snap gauge was used at each pressure step to measure the outer diameter of the balloon. The results are recorded in Table III.

Table III

				BALLOON COMPLIANCE				
Pressure in ATM	Example 19	Example 20	Example 21	Example 22	Example 23	Example 24	Example 25	Example 26
7	0.1208	0.1208	0.1209	0.1209	0.1210	0.1204	0.1208	.1208
8	0.1218	0.1234	0.1234	0.1222	0.1234	0.1213	0.1222	.1219
9	0.1229	0.1244	0.1255	0.1233	0.1259	0.1228	0.1246	.1226
10	0.1245	0.1273	0.1270	0.1245	0.1279	0.1238	0.1271	.1234
11	0.1259	0.1293	0.1284	0.1256	0.1300	0.1253	0.1292	.1239
12	0.1276	0.1307	0.1305	0.1267	0.1312	0.1270	0.1311	.1254
13	1.1296	0.1322	0.1315	0.1279	0.1325	0.1288	0.1338	.1267
14	0.1320	0.1337	0.1335	0.1290	0.1333	0.1307	0.1368	.1279
15	0.1338	0.1347	0.1361	0.1302	0.1341	0.1330	0.1411	.1295
16	0.1355	0.1366	0.1376	0.1317	0.1349	0.1349	0.1477	.1315
17	0.1377	0.1381	0.1392	0.1332	0.1362	0.1375		.1329
18	0.1409	0.1395	0.1412	0.1347	0.1370	0.1421		.1346

WHAT IS CLAIMED IS:

1. A substantially non-polyester substantially non-polyamide medical device comprising polymers or polymeric compositions, wherein the glass transition temperature for the polymer or polymeric composition ranges from about 20 °C to about 100°C.

2. The substantially non-polyester substantially non-polyamide medical device of claim 1, wherein the polymer or polymeric composition possesses a glass transition temperature that ranges from about 20°C to about 65°C.

3. The medical device of claim 1, wherein the medical device is minimally invasive.

4. The medical device of claim 3, wherein the medical device comprises an intraluminal tubular member.

5. The medical device of claim 4, where the medical device comprises an intraluminal balloon.

6. The medical device of claim 1, wherein the polymer or polymeric composition comprises aliphatic polyketone.

7. A substantially non-polyester substantially non-polyamide medical device comprising polymer or polymeric compositions, wherein the polymer or polymeric compositions possess a bulk elongation ranging from about 100 to about 1000 percent, and a bulk tensile strength ranging from about five to about twelve kpsi.

8. The substantially non-polyester substantially non-polyamide medical device of claim 7, wherein the polymer or polymeric composition possesses a bulk elongation ranging from about 200 to about 600 percent, and a bulk tensile strength ranging from about seven to about ten kpsi.

9. The medical device of claim 7, wherein the medical device is minimally invasive.

10. The medical device of claim 9, wherein the medical device comprises an intraluminal tubular member.

11. The medical device of claim 10, where the medical device comprises an intraluminal balloon.

12. The medical device of claim 7, wherein the polymer or polymeric composition comprises aliphatic polyketone.

13. A substantially non-polyester substantially non-polyamide medical device comprising polymer or polymeric compositions, wherein the polymer or polymeric compositions possess a bulk elongation ranging from about 100 to about 1000 percent, and an axial tensile strength of the substantially non-polyester substantially non-polyamide medical device ranges from about ten to about fourty kpsi.

14. The substantially non-polyester substantially non-polyamide medical device of claim 13, wherein the polymer or polymeric compositions possess a bulk elongation ranging from about 200 to about 600 percent, and wherein the axial tensile strength of the substantially non-polyester substantially non-polyamide medical device ranges from about 15 to about 30 kpsi.

15. The medical device of claim 13, wherein the medical device is minimally invasive.

16. The medical device of claim 15, wherein the medical device comprises an intraluminal tubular member.

17. The medical device of claim 16, where the medical device comprises an intraluminal balloon.

18. The medical device of claim 13, wherein the polymer or polymeric composition comprises aliphatic polyketone.

19. A substantially non-polyester substantially non-polyamide medical device comprising polymer or polymeric compositions, wherein the polymer or polymeric compositions possess a bulk elongation ranging from about 100 to about 1000 percent, and the tangential tensile strength of the substantially non-polyester substantially non-polyamide medical device ranges from about ten to about fourty kpsi.

20. The substantially non-polyester substantially non-polyamide medical devices of claim 19, wherein the polymer or polymeric compositions possess a bulk elongation ranging from about 200 to about 600 percent, and wherein the tangential tensile strength of the substantially non-polyester substantially non-polyamide medical device ranges from about 15 to about 30 kpsi.

21. The medical device of claim 19, wherein the medical device is minimally invasive.

22. The medical device of claim 21, wherein the medical device comprises an intraluminal tubular member.

23. The medical device of claim 22, where the medical device comprises an intraluminal balloon.

24. The medical device of claim 19, wherein the polymer or polymeric composition comprises aliphatic polyketone.

25. A substantially non-polyester substantially non-polyamide intraluminal balloon comprising a polymer or polymeric composition, wherein the intraluminal balloon possesses a percent growth/atmosphere ranging from about 0.30 to about 1.60.

26. The substantially non-polyester substantially non-polyamide intraluminal balloon of claim 25, wherein the intraluminal balloon possesses a percent growth/atmosphere ranging from about 0.5 to about 1.35.

27. The substantially non-polyester substantially non-polyamide intraluminal balloon of claim 25, wherein the intraluminal balloon comprises an aliphatic polyketone.

28. A medical device comprising a polymer or polymeric composition, wherein the polymer or polymeric composition possesses a bulk elongation ranging from about 500% to about 1200% and a glass transition temperature ranging from about 20°C to about 100°C.

29. The medical device of claim 28, wherein the polymer or polymeric composition possesses a bulk elongation ranging from about 500 % to

about 800 % and a glass transition temperature ranging from about 20°C to about 65°C.

30. The medical device of claim 28, wherein the medical device is minimally invasive.

31. The medical device of claim 30, wherein the medical device comprises an intraluminal tubular member.

32. The medical device of claim 31, where the medical device comprises an intraluminal balloon.

33. The medical device of claim 28, wherein the polymer or polymeric composition comprises aliphatic polyketone.

34. A method of using the medical device of claim 1 to treat a patient.

35. A method of using the medical device of claim 7 to treat a patient.

36. A method of using the medical device of claim 13 to treat a patient.

37. A method of using the medical device of claim 19 to treat a patient.

38. A method of using the medical device of claim 25 to treat a patient.

39. A method of using the medical device of claim 28 to treat a patient.

40. A medical device comprising a polymer or polymeric composition, made by a method comprising:

providing an aliphatic polyketone polymer;

incorporating the aliphatic polyketone polymer into the polymer or polymeric composition; and

incorporating the polymer or polymeric composition into the medical device.

41. The medical device of claim 40, wherein the medical device is minimally invasive.

42. The medical device of claim 41, wherein the medical device comprises an intraluminal tubular member.

43. The medical device of claim 42, where the medical device comprises an intraluminal balloon.

44. A method of making a medical device comprising a composition comprising aliphatic polyketone comprising:

cross-linking the composition comprising aliphatic polyketone by electron beam radiation, heat or ultraviolet light.

45. A medical device comprising aliphatic polyketone.

46. The medical device of claim 45, wherein the medical device is minimally invasive.

47. The medical device of claim 46, wherein the medical device comprises an intraluminal tubular member.

48. The medical device of claim 47, where the medical device comprises an intraluminal balloon.

49. A composition comprising at least one aliphatic polyketone and at least one plasticizer.

50. The composition of claim 49, wherein the plasticizer comprises aromatic sulfonamide, aromatic phosphate ester, alkyl phosphate ester, alkyl ester, citrate ester, butyl benzosulfonamide, acetate, adipate, amide, azelate, epoxide, glutarate, N,N-dimethyl caprylamide capramide, N,N-dimethyl oleamide, epoxidized glycol dioleate, or analogs or derivatives or mixtures thereof.

51. The composition of claim 49, further comprising customary additives and processing aids.

52. The composition of claim 49, wherein the total amount of plasticizers, additives and other materials comprises less than about 20 weight percent based on the total composition weight.

53. A medical device comprising at least one aliphatic polyketone polymer or a composition of at least one aliphatic polyketone and at least one plasticizer.

54. The medical device of claim 53, wherein the plasticizer comprises aromatic sulfonamide, aromatic phosphate ester, alkyl phosphate ester, alkyl ester, citrate ester, butyl benzosulfonamide, acetate, adipate, amide, azelate, epoxide, glutarate, N,N-dimethyl caprylamide capramide, N,N-dimethyl oleamide, epoxidized glycol dioleate, or analogs or derivatives or mixtures thereof.

55. The medical device of claim 53, further comprising customary additives and processing aids.

56. The medical device of claim 53, wherein the total amount of plasticizers, additives and other materials comprises less than about 20 weight percent based on the total composition weight.

57. The medical device of claim 53, wherein the medical device is minimally invasive .

58. The medical device of claim 57, wherein the plasticizer comprises aromatic sulfonamide, aromatic phosphate ester, alkyl phosphate ester, alkyl ester, citrate ester, butyl benzosulfonamide, acetate, adipate, amide, azelate, epoxide, glutarate, N,N-dimethyl caprylamide capramide, N,N-dimethyl oleamide, epoxidized glycol dioleate, or analogs or derivatives or mixtures thereof.

59. The medical device of claim 57, further comprising customary additives and processing aids.

60. The medical device of claim 57, wherein the total amount of plasticizers, additives and other materials comprises less than about 20 weight percent based on the total composition weight.

61. The medical device of claim 58, where the medical device comprises a percutaneous and non-intraluminal device.

62. The medical device of claim 61, wherein the plasticizer comprises aromatic sulfonamide, aromatic phosphate ester, alkyl phosphate ester, alkyl ester, citrate ester, butyl benzosulfonamide, acetate, adipate, amide, azelate, epoxide, glutarate, N,N-dimethyl caprylamide capramide, N,N-dimethyl oleamide, epoxidized glycol dioleate, or analogs or derivatives or mixtures thereof.

63. The medical device of claim 61, further comprising customary additives and processing aids.

64. The medical device of claim 61, wherein the total amount of plasticizers, additives and other materials comprises less than about 20 weight percent based on the total composition weight.

65. The medical device of claim 53, wherein the medical device comprises an intraluminal tubular member.

66. The medical device of claim 64, wherein the plasticizer comprises aromatic sulfonamide, aromatic phosphate ester, alkyl phosphate ester, alkyl ester, citrate ester, butyl benzosulfonamide, acetate, adipate, amide, azelate, epoxide, glutarate, N,N-dimethyl caprylamide capramide, N,N-dimethyl oleamide, epoxidized glycol dioleate, or analogs or derivatives or mixtures thereof.

67. The medical device of claim 65, further comprising customary additives and processing aids.

68. The medical device of claim 65, wherein the total amount of plasticizers, additives and other materials comprises less than about 20 weight percent based on the total composition weight.

69. The medical device of claim 65, where the medical device comprises a percutaneous and non-intraluminal device.

70. The medical device of claim 65, where the medical device comprises an intravascular catheter.

71. The medical device of claim 65, where the medical device comprises an intracornoary catheter.

72. The medical device of claim 65, where the medical device comprises a percutaneous device.

73. The medical device of claim 65, where the medical device comprises a non-percutaneous device.

74. The medical device of claim 57, where the medical device comprises an intraluminal balloon.

75. The medical device of claim 74, wherein the plasticizer comprises aromatic sulfonamide, aromatic phosphate ester, alkyl phosphate ester, alkyl ester, citrate ester, butyl benzosulfonamide, acetate, adipate, amide, azelate, epoxide, glutarate, N,N-dimethyl caprylamide capramide, N,N-dimethyl oleamide, epoxidized glycol dioleate, or analogs or derivatives or mixtures thereof.

76. The medical device of claim 74, further comprising customary additives and processing aids.

77. The medical device of claim 74, wherein the total amount of plasticizers, additives and other materials comprises less than about 20 weight percent based on the total composition weight.

78. The medical device of claim 74, where the medical device comprises a percutaneous device.

79. The medical device of claim 74, where the medical device comprises a non-percutaneous device.

80. The medical device of claim 74, where the medical device comprises a single balloon.

81. The medical device of claim 74, where the medical device comprises multiple balloons.

82. The medical device of claim 74, wherein the balloon wall material is biaxially oriented.

83. The medical device of claim 74, wherein the balloon is about 1.5 to 12 mm in diameter.

84. The medical device of claim 74, wherein the balloon is capable of deploying a stent.

85. The medical device of claim 74, wherein the balloon is semi-compliant.

86. The medical device of claim 74, wherein the balloon wall material is perforated or is sufficiently porous to permit drug delivery through the wall material.

87. A medical device comprising a composition that comprises an aliphatic polyketone and a thermoplastic polymer.

88. The medical device of claim 87, wherein the composition comprises aliphatic polyketone in an amount of about 5 to about 95 weight percent, based on the total weight of the composition.

89. The medical device of claim 87, wherein the composition comprises a thermoplastic polymer in an amount of about 5 to about 95 weight percent, based on the total weight of the composition.

90. The medical device of claim 87, wherein the thermoplastic polymer is polyamide, polyester, polyether-blockamide, polyurethane, polyethylene, polyacetal, polyacrylonitrile, or polyvinylidene fluoride.

91. The medical device of claim 90, wherein the thermoplastic polymer is polyamide.

92. The medical device of claim 87, wherein the composition further comprises a coupling agent, a plasticizer, or a cross-linker.

93. The medical device of claim 92, wherein the coupling agent is a zirconium or titanium coupling agent, or an epoxy modified polyolefin.

94. The medical device of claim 92, wherein the plasticizer is aromatic sulfonamides, aromatic phosphate esters, alkyl phosphate esters, alkyl esters, citrate esters, butyl benzosulfonamides, acetate, adipate, amides, azelates, epoxides, glutarates such as polyester glutarate, N,N-dimethyl caprylamide capramide, N,N-dimethyl oleamide, epoxidized glycol dioleate, and analogs and derivatives and mixtures thereof.

95. The medical device of claim 92, wherein the cross-linking agent is ethylene glycol dimethacrylate, triallyl isocyanurate, triallyl cyanurate, or triallyl 1,3,5-triazine-2,4,6(1H,3H,5H)-trione.

96. The medical device of claim 87, wherein the medical device is minimally invasive.

97. The medical device of claim 96, wherein the composition comprises aliphatic polyketone in an amount of about 5 to about 95 weight percent, based on the total weight of the composition.

98. The medical device of claim 96, wherein the composition comprises a thermoplastic polymer in an amount of about 5 to about 95 weight percent, based on the total weight of the composition.

99. The medical device of claim 96, wherein the thermoplastic polymer is polyamide, polyethylene, polyacetal, polyacrylonitrile, polyether-blockamide, polyurethane, polyester, or polyvinylidene fluoride.

100. The medical device of claim 96, wherein the composition further comprises a coupling agent, a plasticizer, or a cross-linker.

101. The medical device of claim 96, where the medical device comprises a percutaneous and non-intraluminal device.

102. The medical device of claim 96, wherein the medical device comprises an intraluminal tubular member.

103. The medical device of claim 102, wherein the composition comprises aliphatic polyketone in an amount of about 5 to about 95 weight percent, based on the total weight of the composition.

104. The medical device of claim 102, wherein the composition comprises a thermoplastic polymer in an amount of about 5 to about 95 weight percent, based on the total weight of the composition.

105. The medical device of claim 102, wherein the thermoplastic polymer is polyamide, polyethylene, polyacetal, polyacrylonitrile, polyether-blockamide, polyurethane, polyester, or polyvinylidene fluoride.

106. The medical device of claim 102, wherein the composition further comprises a coupling agent, a plasticizer, or a cross-linker.

107. The medical device of claim 102, where the medical device comprises an intravascular catheter.

108. The medical device of claim 102, where the medical device comprises an intracoronary catheter.

109. The medical device of claim 102, where the medical device comprises a percutaneous device.

110. The medical device of claim 102, where the medical device comprises a non-percutaneous device.

111. The medical device of claim 102, where the medical device comprises an intraluminal balloon.

112. The medical device of claim 111, wherein the composition comprises aliphatic polyketone in an amount of about 5 to about 95 weight percent, based on the total weight of the composition.

113. The medical device of claim 111, wherein the composition comprises a thermoplastic polymer in an amount of about 5 to about 95 weight percent, based on the total weight of the composition.

114. The medical device of claim 111, wherein the thermoplastic polymer is polyamide, polyethylene, polyacetal, polyacrylonitrile, polyether-blockamide, polyurethane, polyester, or polyvinylidene fluoride.

115. The medical device of claim 114, wherein the thermoplastic polymer is polyamide.

116. The medical device of claim 111, wherein the composition further comprises a coupling agent, a plasticizer, or a cross-linker.

117. The medical device of claim 111, where the medical device comprises a percutaneous device.

118. The medical device of claim 111, where the medical device comprises a non-percutaneous device.

119. The medical device of claim 111, where the medical device comprises a single balloon.

120. The medical device of claim 111, where the medical device comprises multiple balloons.

121. The medical device of claim 111, wherein the balloon wall material is biaxially oriented.

122. The medical device of claim 111, wherein the balloon is about 1.5 to 12 mm in diameter.

123. The medical device of claim 111, wherein the balloon is capable of deploying a stent.

124. The medical device of claim 111, wherein the balloon is semi-compliant.

125. The medical device of claim 111, wherein the balloon wall material is perforated or is sufficiently porous to permit drug delivery through the wall material.

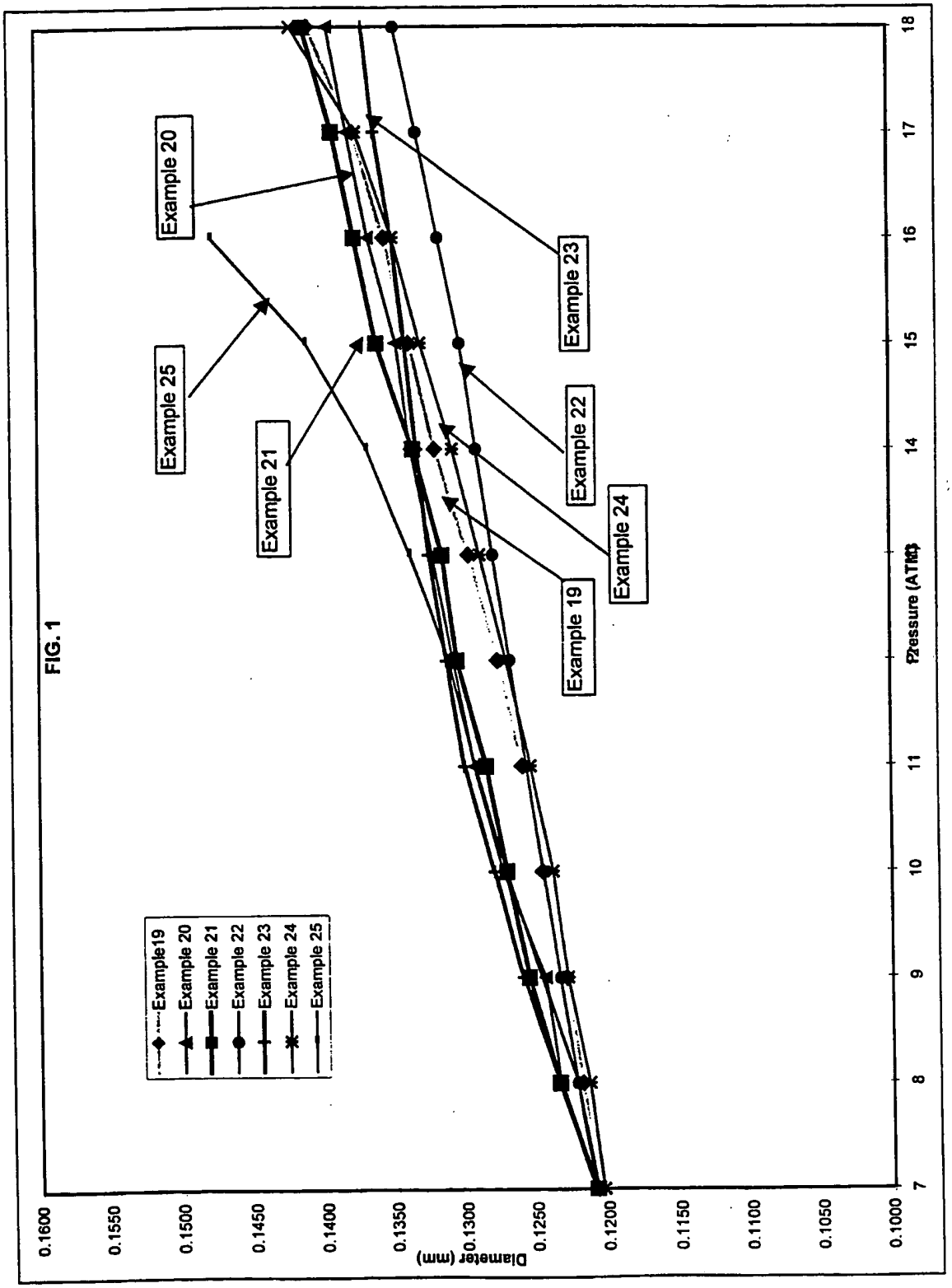

Example 20
Example 25
Example 21
Example 23
Example 22
Example 24
Example 19
Example19
Example 20
Example 21
Example 22
Example 23
Example 24
Example 25
Diameter (mm)
Pressure (ATM)
0.1600
0.1550
0.1500
0.1450
0.1400
0.1350
0.1300
0.1250
0.1200
0.1150
0.1100
0.1050
0.1000
7
8
9
10
11
14
15
16
17
18

FIG. 1